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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

LCM 622-89

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on _____

Signature _____

Typed or printed name _____

Application Number

10/559,794

Filed

December 8, 2005

First Named Inventor

Mailland

Art Unit

1655

Examiner

Tate, C.R.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

/Leonard C. Mitchard/

Signature

☐ assignee of record of the entire interest.

See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

Leonard C. Mitchard

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Registration number _____

703-816-4005

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Registration number if acting under 37 CFR 1.34 _____

July 17, 2009

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☐ *Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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STATEMENT OF ARGUMENTS IN SUPPORT OF
PRE-APPEAL BRIEF REQUEST FOR REVIEW

The following listing of clear errors in the Examiner's rejection and the failure to identify essential elements necessary for a *prima facie* basis of rejection is responsive to the Final Rejection mailed April 17, 2009.

The Office is reminded that the Court of Appeals for the Federal Circuit has held that “the PTO has the burden under Section 103 to establish a *prima facie* case of obviousness.” *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). “It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.”

While the Office “no longer has to show a motivation, teaching, or suggestion within a reference to arrive at the claimed invention to establish a *prima facie case* of obviousness”, the Office is required to do as follows:

“When making an obviousness rejection, Office personnel must therefore ensure that the written record includes **findings of fact** concerning the state of the art and the teachings of the references applied. In certain circumstances, it may also be important to include explicit findings as to how a person of ordinary skill would have understood prior art teachings, or what a person of ordinary skill would have known or could have done. Factual findings made by Office personnel are the necessary underpinnings to establish obviousness.” *See Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc.* 57526, 57527 Federal Register/Vol. 72, No. 195 (Emphasis added).

Claims 25, 26, 49, 58, 63, 65, 67, 68, 71-73, and 78 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Godbout (US 2004/0013622) and the admitted state of the art. Claims 27-29, 48, 51-62, 64, 66-70, and 74-80 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Godbout in view of the admitted state of the art and further in view of Ramin (US 5,607,768) and Moeller *et al.* (DE 19826953 WPINDEX Abstract), and further in view of the PDR® for Herbal Medicines (1998) and Koniger (WO 94/2504 1; Derwent abstract and machine English translation).

The claimed invention is directed to a method for the treatment of onychoschizia in a patient having onychoschizia. The method comprises administering to the patient a topical composition comprising:

- a) at least one herb extract from the genus *Equisetum*, and
- b) at least one film forming agent.

Error #1. The Action Fails to Provide Specific Findings of Fact in Support of the Obviousness Rejections

Godbout (as the Action admits) does not expressly disclose treating a subject having onychoschizia with a composition comprising an *Equisetum*. The Action asserts that the claimed method is rendered obvious over Godbout in view of Applicant's alleged admission that onychoschizia is a widespread condition found in 27-35% of normal adult women, that it affects mainly housewives, workmen, and workwomen, and that exogenous factors that contribute to onychoschizia include people who carry out a great deal of housework including those whose nails are repeatedly soaked in water and then dried (pages 2-3 of the instant specification). This assertion is not correct.

While the statement at pages 2-3 of the specification may reflect the state of the art prior to when the case was filed, the combination of this state of the art with Godbout does not give rise to a *prima facie* case of obviousness of the presently claimed method, because there is no suggestion in those two disclosures, taken singly or in combination, of a method of treating a patient having the **specific condition known as onychoschizia** by administering a topical composition to the nail comprising (a) at least one herb extract from the genus *Equisetum*, and (b) at least one film forming agent. The Action therefore fails to provide specific findings of fact in support of the allegation of obviousness. Absent any suggestion **in either disclosure** specifically of treatment of onychoschizia, no *prima facie* case of obviousness arises.

Error #2. The Action Fails to Accord Proper Weight to the Mailland Declaration

As described in the present specification (pages 3 and 4), and as confirmed by the Mailland declaration and Enclosure 1 thereto (copy attached to the Mailland declaration), onychoschizia is **NOT** a generic condition of nail brittleness, but rather a specific and well-characterized pathology of the nails, wherein the distal portion of the nail splits horizontally. The Mailland declaration states that while the PDR for Herbal Medicine (PDR) reports that *Equisetum* may be used for the treatment of "brittle finger nails and loss of hair", the efficacy of such use "is not proven". Moreover, there is no suggestion in PDR to apply *Equisetum* topically onto nails in the treatment of onychoschizia, as required by the presently claimed method.

The Mailland declaration goes on to state that onychomycosis and onychoschizia are "different and unrelated conditions", and require "two completely different treatments". In particular, as stated in the Mailland declaration referring to Enclosure 2 thereof (copy attached to the Mailland declaration), onychomycosis is a fungal infection of the nails, caused by specific

microorganisms, and its treatment requires the use of antimycotic agents. In this pathology, the nail structure is damaged by fungi that grow inside the nail and render the nail more fragile. The Mailland declaration states that onychomycosis is never a cause of onychoschizia, but it is frequently a cause of onycholysis, i.e., a detachment of the full nail plate from the nail bed.

The Mailland declaration in addition discusses Example 10 of the present application, which describes the results of a study of subjects previously affected by onychomycosis. The Mailland declaration notes that, after treatment with the claimed composition, no effect was seen in these subjects regarding onycholysis, whereas a definite improvement was recorded with onychoschizia (a significant improvement ($p < 0.001$) was observed compared to untreated nails).

Based on the Mailland declaration, it is clear that onychoschizia is understood in the art to be a **specific** and well-characterized pathology of the nails, wherein the distal portion of the nail splits horizontally. Onychoschizia is clearly **not** a generic condition of nail brittleness. This is described in the present specification at paragraphs [0008] and [0012].

As Godbout, taken alone or in combination with the specification disclosure, does not suggest the claimed invention for the reasons discussed above, it is clear that the remaining secondary art cited in the Action (Ramin, Moeller, PDR for Herbal Medicines (1998) and Koniger) does not give rise to a *prima facie* of obviousness of the claimed method taken alone or in combination with Godbout and/or the specification disclosure.

SUMMARY

The Office has failed to meet his burden of establishing a *prima facie* case of obviousness. Neither Godbout nor the state of the art as discussed in the present application relates to or suggests the treatment of onychoschizia by the claimed method. Moreover, the combination of Godbout and the disclosure of the present specification fails to give rise to a

prima facie case of obviousness of the claimed invention. The remaining secondary art relied upon in the obviousness rejection likewise fails to give rise to a *prima facie* case of obviousness.

Applicant therefore respectfully requests that the Pre-Appeal Panel find that the application is allowable on the existing claims. Early notice to that effect is awaited.